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14. ABSTRACT

Breast cancer survivors are at elevated risk for developing a new breast cancer compared to healthy women, and are at considerable risk for breast cancer recurrence. According to the American Society of Clinical Oncology, survivors should undergo careful breast cancer surveillance including annual mammography and breast self-exam. However, studies indicate that breast cancer surveillance among African American survivors, particularly mammography, is low, especially given the higher risk of survivors as a group. The promotion of breast cancer surveillance among African American survivors is an area that deserves special attention as cancers detected early are more treatable. The primary objective of the current study is to test the impact of a DVD intervention among 120 African American breast cancer survivors by comparing 2 randomized groups at baseline and 3-month follow-up

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INTRODUCTION: Breast cancer survivors are at elevated risk for developing a new breast cancer compared to healthy women, and are at considerable risk for breast cancer recurrence. According to the American Society of Clinical Oncology, survivors should undergo careful breast cancer surveillance including annual mammography and breast self-exam. However, studies indicate that breast cancer surveillance among African American survivors, particularly mammography, is low, especially given the higher risk of survivors as a group. The promotion of breast cancer surveillance among African American survivors is an area that deserves special attention as cancers detected early are more treatable. One promising strategy is the adaptation of a peer-led intervention developed to increase screening among healthy African American women. The objectives of the current study are: 1) to evaluate the impact of a peer-led intervention on breast cancer surveillance intention and adherence among African American breast cancer survivors through a randomized controlled trial; and 2) to investigate the mediational pathways through which the peer-led intervention impacts surveillance intention and adherence. 409 participants will be recruited and randomized over the course of the study. Participants will be African American women age 20-74 years and diagnosed with Stage I, II or III breast cancer who previously participated in an ongoing parent project and are at least 3 months post-treatment. Once informed consent is obtained, participants will be contacted via telephone to complete a baseline interview assessing sociodemographic information, breast cancer surveillance intention and adherence, and attitudinal/cognitive variables. Participants will then be assigned to either the survivor surveillance intervention condition or control condition and those in the intervention condition will participate in the intervention. One month following the intervention, participants in both conditions will complete a telephone interview to assess breast cancer screening adherence and changes in attitudinal/cognitive variables from baseline to post-intervention. Fourteen months after the intervention, women in both conditions will be contacted again in order to assess surveillance intention and adherence.

BODY: In June 2007, a one-year no-cost extension was granted. In April of 2008, a change to the SOW was approved. In order to address the feasibility, we sought and obtained funding in 2007 through the Susan G. Komen for the Cure Breast Cancer Disparities Research Award to convert the live SIS intervention into DVD format (performance period 9/21/07 – 9/20/09). The aims of this new study are 1) to develop a DVD intervention based on SIS to promote post-treatment breast cancer surveillance among African American breast cancer survivors that is guided by focus group input; 2) to conduct a pilot evaluation of the cognitive and psychological impact of the SIS-DVD intervention using standardized questionnaires; and 3) to disseminate results of the SIS-DVD evaluation via educational seminars targeting African American breast cancer survivors as well as healthcare providers and advocacy groups. After initial production of the SIS-DVD, we will conduct two focus groups of AA breast cancer survivors to obtain feedback using standard focus group methods. Once this feedback is analyzed, these results will guide the final edit of the SIS video to be used in the questionnaire component of the project. In this component, 60 AA breast cancer survivors will be a recruited through physician referral. These participants will complete a single pre-test/intervention/post-test session.

As part of the revised SOW, we added new component in which we will test the impact of the SIS DVD intervention among 120 African American breast cancer survivors by comparing 2 randomized groups at baseline and 3-month follow-up: 1) participants shown the SIS DVD intervention and 2) participants shown a control health DVD intervention. The primary hypothesis is that participants in the survivor surveillance intervention condition will report greater breast cancer surveillance intention and adherence following that intervention compared to women in the control group.

Revised SOW

I. Months 1-17 <u>THIS WORK HAS BEEN COMPLETED AT MOUNT SINAI SCHOOL OF MEDICINE (MSSM)</u>

b. Hire and train research staff

c. Develop live, peer-led intervention: Survivors in Spirit (SIS)
    1. Recruit and coordinate an advisory board to provide feedback on intervention content
d. Prepare peer interventionists
    1. Identify and recruit survivors and non-diagnosed women as interventionists
    2. Conduct group and individual training sessions
    3. Evaluate impact of training curriculum
e. Collaborate with co-investigators and consultants to review assessment strategies and tailoring of the survivor surveillance intervention
    1. Pilot test and refine measures
f. Develop data entry and participant tracking systems

II. Months 18 - 32 <u>THIS WORK HAS BEEN COMPLETED AT MSSM</u>

A. Review database of parent project to identify eligible breast cancer patients
a. Recruit and consent 60 patients for randomized controlled trial via telephone
b. Administer baseline assessment and 1 –month follow-up interview for randomized controlled trial via telephone
c. Randomize participants and coordinate SIS intervention programs
    1. Identify appropriate SIS program sites
    2. Coordinate a team of peer interventionists for each SIS program
    3. If necessary, provide transportation for interventionists and participants
    4. Collect data on immediate post-intervention evaluation from study participants
d. Commence data entry and management

III. Months 32-38 <u>THIS WORK HAS BEEN COMPLETED AT MSSM</u>

A. Expand recruitment strategies via outreach to New York Hospital Queens and Kings County Hospital
    1. Identify site PIs
    2. Obtain site IRB approvals
    3. Collaborate with site PIs to review patient charts and tumor registries to identify potential patients
    4. Continue recruitment efforts
B. Collaborate with other studies to promote individual referral from other sites
    1. Conduct informational presentations at hospitals, clinics, and survivor advocacy group meetings

IV. *Months 32-48 <u>THIS WORK HAS BEEN COMPLETED AT MSSM</u>*

a. Commence contact of participants via telephone to administer 14-month follow-up assessment interviews
b. Continue data entry and management
c. Work with co-investigators and consultants to conduct analyses for report
d. Prepare manuscripts for publication

VI.* Months 49 – 60 *<u>COMPLETED AT MSSM THROUGH KOMEN FUNDING</u>

A. Re-assess feasibility of live peer intervention
B. Use data from intervention development, baseline and follow-up assessments to develop a DVD intervention based on SIS (Currently funded by Susan G. Komen for the Cure 9/21/07 – 9/20/09).
C. Develop DVD intervention
D. Obtain feedback on DVD content via focus groups

VII. Months 61 – 72 ***WORK TO BE COMPLETED AT ALBERT EINSTEIN COLLEGE OF MEDICINE (AECOM) DURING EXTENSION PERIOD (6/9/09 – 6/8/10)***

A. Evaluate the impact of the DVD on cognitive and emotional outcomes among 60 African American breast cancer survivors in a single pre-test/intervention/post-test session. ***TO BE COMPLETED AT AECOM THROUGH KOMEN FUNDING***

B. Test the impact of the DVD intervention among 120 African American breast cancer survivors by comparing 2 randomized groups at baseline and 3-month follow-up ***TO BE COMPLETED AT BOTH MSSM & AECOM THROUGH DOD FUNDING***

1. Participants shown the SIS DVD intervention
2. Participants shown a control health DVD intervention

KEY RESEARCH ACCOMPLISHMENTS:

As part of the Komen grant (for which we are in the process of obtaining a no-cost extension), we completed two focus groups of breast cancer survivors to provide initial evaluations of the content of the DVD. We are currently in the process of recruitment for both the evaluation of the impact of the DVD on cognitive and emotional outcomes among 60 African American breast cancer survivors (as part of the Komen grant) in a single pre-test/intervention/post-test session. Through this recruitment process, we will also recruit participants to test the impact of the DVD intervention among 120 African American breast cancer survivors by comparing 2 randomized groups at baseline and 63month follow-up.

REPORTABLE OUTCOMES: There are no reportable outcomes at this time specific to the revised SOW.

CONCLUSIONS: At this time, we are actively recruiting participants for the study and are in compliance with the proposed study timeline and statement of work.